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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,142

06/20/2003

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT

PAPER NUMBER

1623

MAIL DATE

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02/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/602,142	Applicant(s) SOMMADOSSI ET AL.	
	Examiner TRAVISS C. MCINTOSH III	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89, 130-141, 143-158 and 160-194 is/are pending in the application.
- 4a) Of the above claim(s) 188-191 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89, 130-141, 143-158, 160-187, 192-194 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/13/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed 10/31/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 143, 148, and 152-154 have been amended.

Claims 188-194 have been added

Claims 1-88, 90-129, 142, and 159 have been canceled.

Remarks drawn to rejections of Office Action mailed 9/20/2007 include:

Double Patenting Rejections: which have been maintained for reasons of record.

An action on the merits of claims 89, 130-141, 143-158, and 160-194 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

Newly submitted claims 188-191 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are drawn to a different statutory class of invention; products versus methods of use.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 188-191 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claims 192-194 are objected to for depending from a withdrawn claim. It is noted the examiner is interpreting these claims as treating HCV with the compound of claim 188 even though the compound claims are withdrawn.

Double Patenting

The rejection of claims 89 and 130-187 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 7,163,929 is maintained for reasons of record. Newly added claims 192-194 are rejected herein additionally for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim methods of treating viral infections using pyrrolopyrimidine nucleosides, and alternately in combination with the same additional anti-viral agents. It is noted that the '929 patent is drawn to treating flavivirus or pestivirus

Art Unit: 1623

infections and the instant application is drawn to treating HCV infections, however, the Flaviviridae family of viral infections is known to include flavivirus, pestivirus and HCV, as such, it would be obvious to treat various members of the Flaviviridae family of viruses with the same composition. It would be obvious to one of ordinary skill in the art that the instant application and the '929 patent are substantially overlapping.

Applicants argue that the '929 patent is drawn to treating flavivirus or pestivirus infections, and the instant claims are drawn to treating HCV, which is not a flavivirus or pestivirus. This is not found convincing. The Flaviviridae virus family contains both flavivirus and HCV viruses, and it would be prima facie obvious to practice the invention of the '929 patent on another member of the Flaviviridae virus family, HCV. Applicants also argue that HCV belongs to a different genus than flavivirus and pestivirus, as HCV is a hepacivirus. The examiner does not dispute this, but notes that all three, flavivirus, pestivirus, and hepacivirus all belong to the family of viruses of Flaviviridae, and although the viruses belonging to the different genera have different biological properties and do not show serological cross-reactivity, great similarity in terms of virion morphology, genome organization, and presumed replication strategy have been noted. At the minimum, the examiner notes that it would be obvious to try a method of treating HCV in light of the references teaching to treat pestivirus and flavivirus infections with overlapping compounds. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

KSR, 550 U.S. at ___, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

(E) “ Obvious to try ” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.

In the instant case, there is a finite number of genera within the Flaviviridae family, and a teaching that therapy against two of those members would afford the skilled artisan a reasonable expectation of success in practicing the instantly claimed method in light of that teaching.

Applicants also argue that the policy behind double patenting rejection is the prevention of an unjustified extension of the term of a patent, which does not support the examiners rejection in this case. However, the examiner agrees that the purpose of double patenting rejections is to prevent an unjustified extension of the term of a patent, however it is also appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). As such, absent evidence to the contrary, the examiner believes the instant methods of treating HCV are obvious over the patent's claims to methods of treating flavivirus and pestivirus infections.

The provisional rejection of claims 89 and 130-187 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-17 and 19-75 of copending Application No. 11/005,472 is maintained for reasons of record. Newly added claims 192-194 are rejected herein additionally for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim methods of treating HCV using pyrrolopyrimidine nucleosides, and alternately in combination with the same additional anti-viral agents. It is noted that the '472 application is drawn to 3'-prodrugs of the compounds used in the instant application, however, it is noted that the 3'-position of the instant application are optionally amino acid esters. As such, it would be obvious that the instant application and the '472 application are indeed overlapping in that both claim methods of treating HCV with overlapping pyrrolopyrimidine nucleotides having a '3-amino acid prodrug moiety. Obviousness based on similarity of structure and function entails motivation to make claimed compound in the expectation that compounds similar in structure will have similar properties. Where the prior art compounds essentially bracket the claimed compounds and are known to be effective as well known pesticides, for example, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new pesticides. See **In re Payne**, 606 F.2d 303, 203 USPQ 245, 254-55 (CCPA 1979). Prodrug esters are well known in the art, as are amino acid prodrug esters, as such, absent unexpected results, the examiner believes it would be obvious to make the 3'-amino-acid prodrug esters of the '472 application.

It is noted applicants argued that since the only rejections left are provisional rejections, then the case should be issued according to MPEP 804, subsection I.B. However, since there are still pending rejections, this is not found persuasive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRAVISS C. MCINTOSH III whose telephone number is (571)272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh
February 18, 2008
Art Unit 1623

/Traviss C McIntosh III/
Art Unit 1623